

The Global PrEP Research Landscape: Mapping studies of oral PrEP implementation and impact

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**OPTIONS refers to PrEP as the product category (inclusive of all formulations of ARV-based HIV prevention), and refers to specific products by formulation designation and/or name (e.g. oral PrEP/TDF-FTC, topical PrEP/dapivirine ring, injectable PrEP/cabotegravir, etc).*

BACKGROUND

Oral pre-exposure prophylaxis (PrEP) has gained acceptability as a major tool for prevention since it was first approved by the United States FDA in 2012. Since that time, at least 68 countries have begun offering oral PrEP in some form, ranging from stand alone demonstration projects to full national rollout, but as oral PrEP is brought to scale, there are many key questions still to be answered. In order to consolidate learnings on PrEP and enhance understanding of the global research landscape, AVAC began tracking global oral PrEP projects/studies in 2014 and now maintains a comprehensive database for the OPTIONS Consortium.

METHODS

Overview

A mapping of completed, ongoing and planned oral PrEP projects and studies from 2014-2018 was conducted using survey data collected quarterly through December 2018. For the purpose of this review, the most recent survey collected from each project was included.

The survey is distributed quarterly to all known ongoing and planned demonstration projects, implementation projects and clinical trials which provide oral PrEP. The survey sample has expanded substantially since the survey was initiated, and has expanded from 49 projects and studies worldwide to 191 as of December 2018. The survey is sent via email to study coordinators and principal investigators for completion, and all updates are consolidated in the first month of the subsequent quarter. The survey is a mix of multiple choice and open-ended questions, covering a range of topics including participant demographics, geography, funding, service-delivery settings, program types, tools created, resistance testing, research questions and outcomes.

Inclusion Criteria

For the purpose of this review, survey responses were collected from all known demonstration projects, implementation studies or open-label clinical trials that provide oral PrEP *and* have a clear research objective outlined in their protocols.

Scope

Programs were mapped based on the following criteria:

- Geography
- Size and population
- Research questions

Additionally, research questions from the projects/studies were mapped along the product introduction framework (see figure 1) to analyze and identify gaps and overlaps.

Figure 1. The Product Introduction Framework



RESULTS

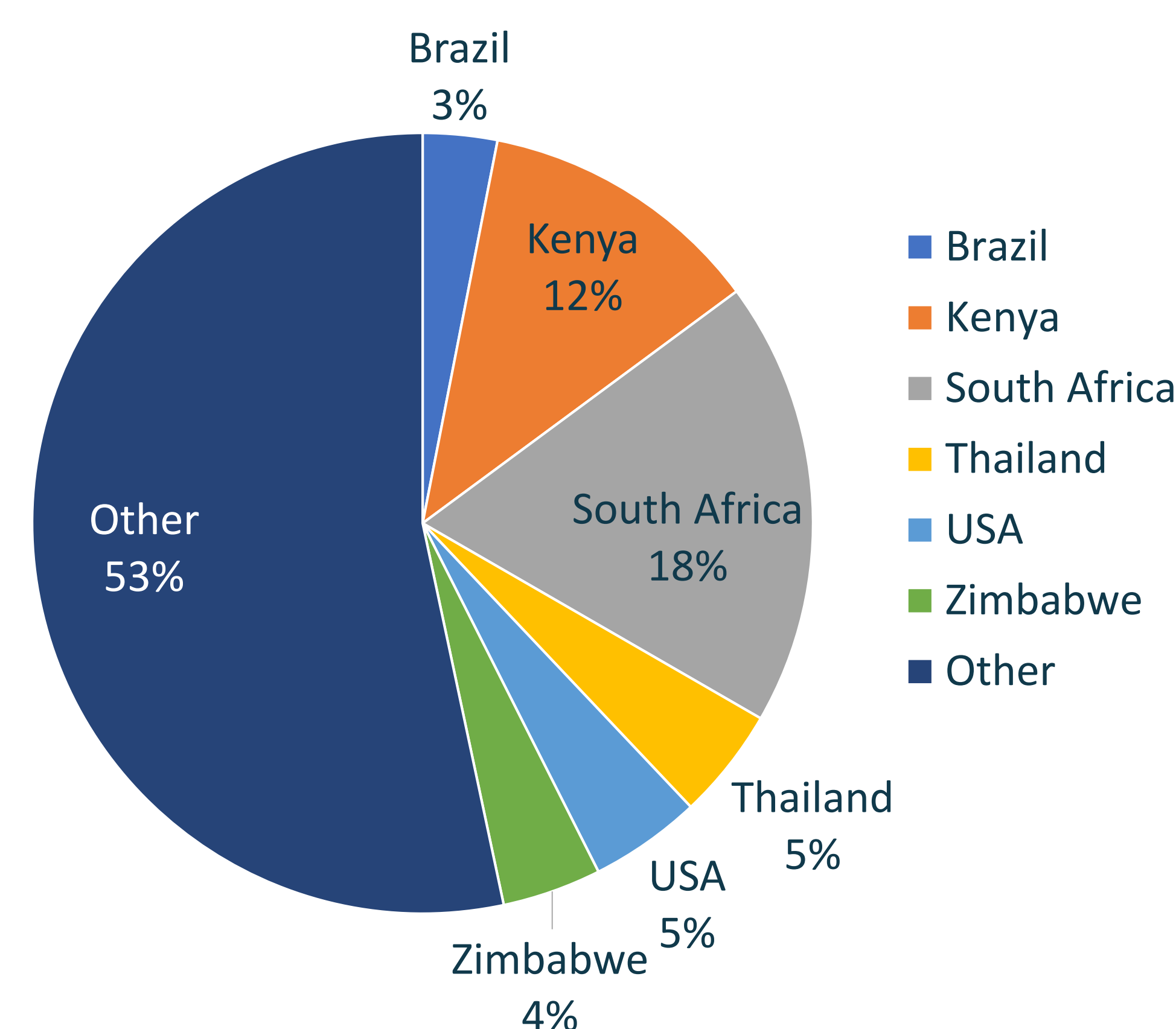
Project/Study Distribution Across Geographies

Overall, this mapping identified 112 organizations working on 191 projects or studies in 68 countries around the globe. Projects/studies were distributed across regions with high and low HIV prevalence, with the highest concentration observed in South Africa, Kenya, Thailand, the United States, Zimbabwe and Brazil; these countries respectively held 47% of all PrEP projects/studies worldwide, with South Africa and Kenya contributing the greatest number, at 18% and 11% of the global total.

Figure 2. Global Snapshot of the oral PrEP Research Landscape



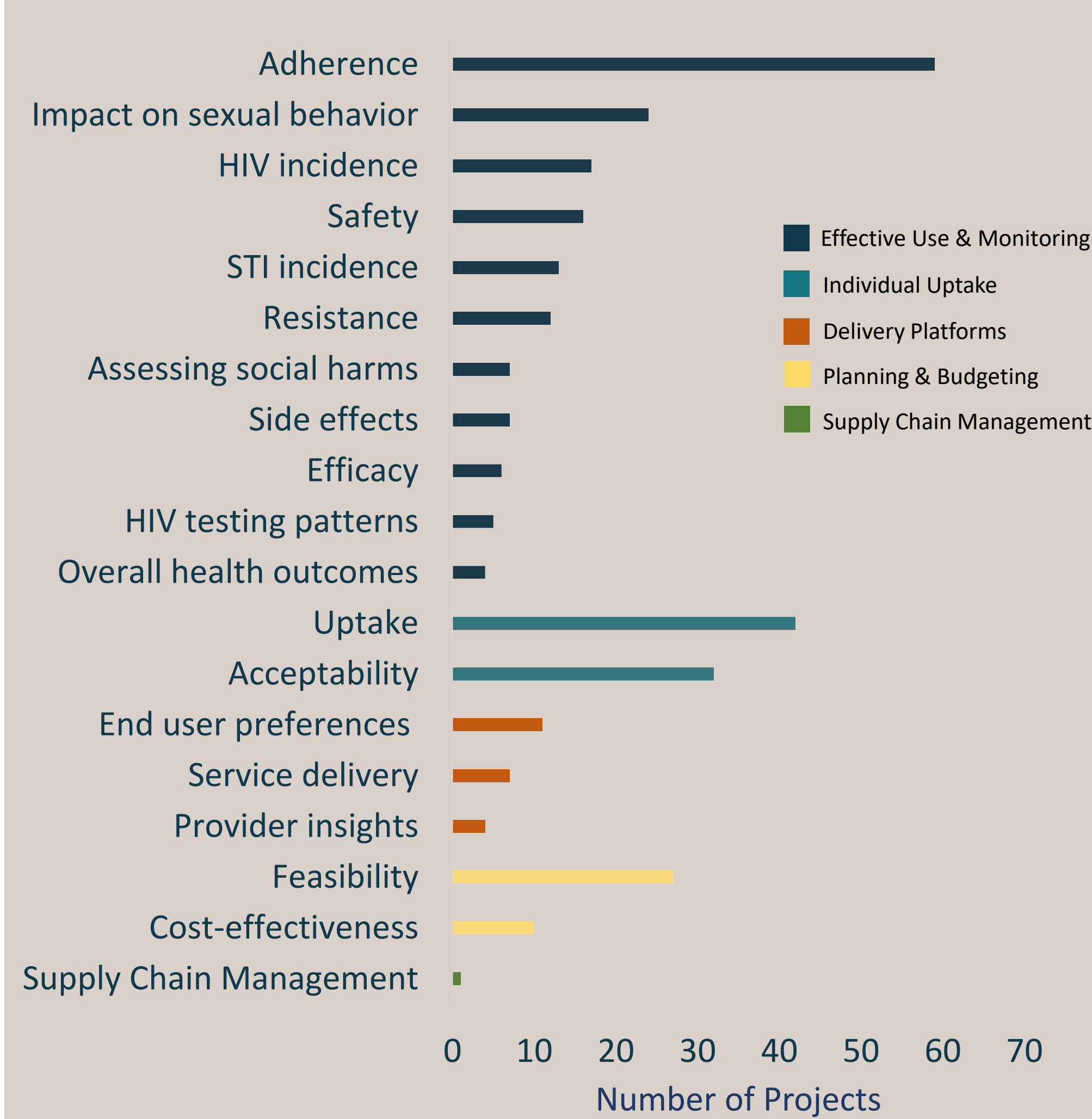
Figure 3. Distribution of Projects/Studies by Country



Mapping Oral PrEP Research Questions

Mapping research questions along the product introduction framework demonstrated that the majority of projects/studies had research questions focused on *individual uptake* and *effective use and monitoring*. The most common issues examined were those related to adherence, uptake, acceptability and feasibility, risk behaviors, HIV incidence and drug safety. Conversely, few projects/studies examined questions related to provider support, end user preferences for service delivery, or generating demand for HIV prevention or supply chain management – key areas that have proven critical for effective HIV prevention programming.

Figure 4. Oral PrEP Research Question Topics

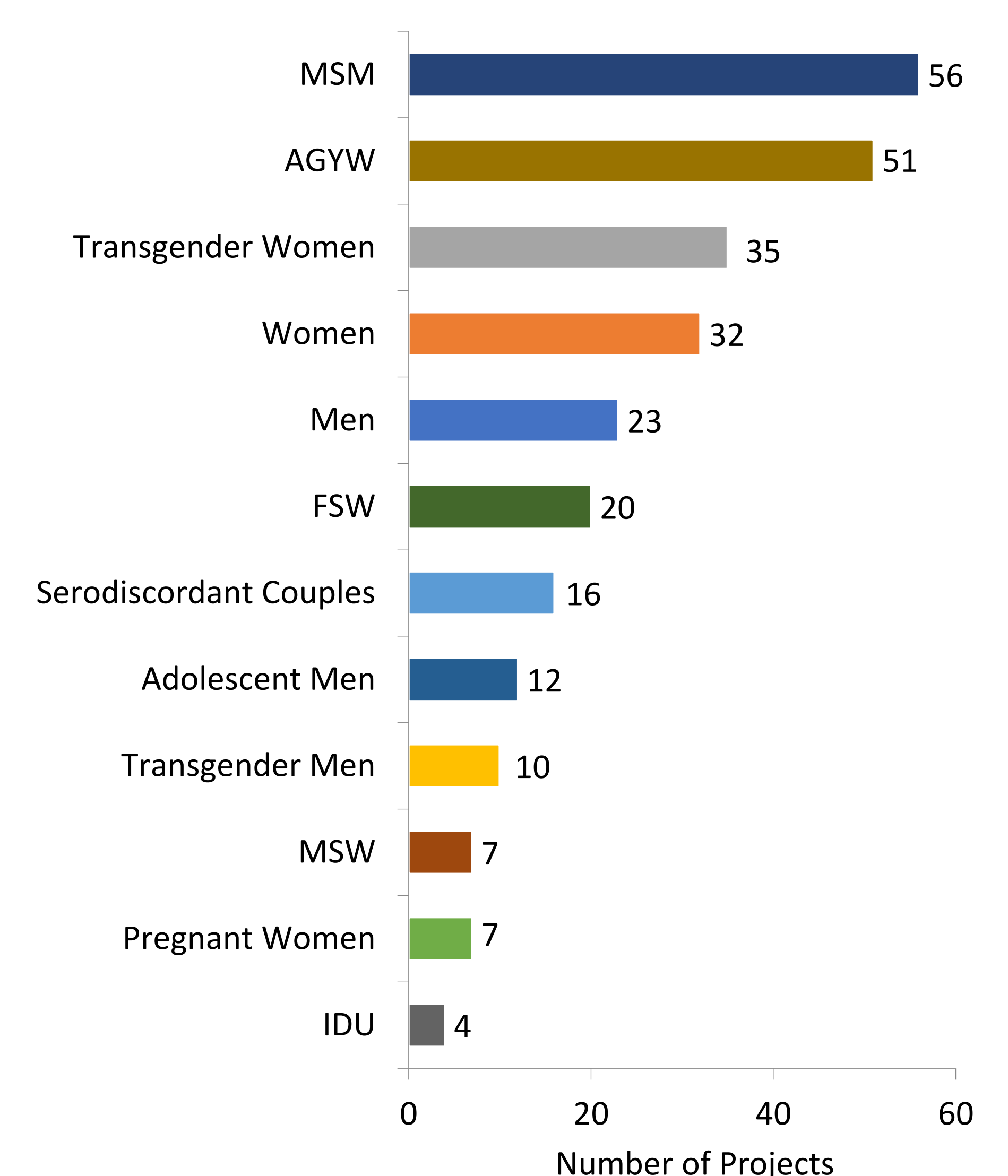


RESULTS

Project/Study Size and Demographics

Notably, 89% of all projects/studies mapped involved less than 1,000 individuals each. Of the 21 projects with enrollment numbers greater than 1000 individuals, the majority were supported by PEPFAR (a total of 39%). Across all projects/studies, the most commonly served populations were men who have sex with men (MSM), female sex workers (FSW), and adolescent girls and young women (AGYW). Regionally, the majority of research in North America was geared towards MSM, while in sub-Saharan Africa the research focused primarily on AGYW, reflecting in part the differences between each region's epidemic.

Figure 5. Number of Projects/Studies by Target Population



CONCLUSIONS

Mapping projects and studies across the globe reveals several gaps in the research on oral PrEP, including the lack of implementation research focused on provider support, demand creation and user preferences for service delivery. Globally, oral PrEP projects/studies were designed to answer many similar questions around *individual uptake* and *effective use and monitoring*, with less emphasis on the services that accommodate and communications that appeal to those at high-risk. A lack of research on service delivery and supply chain challenges in early stages of research in-country may limit the ability of many projects/studies to maximize efficiencies and accessibility during rollout. **Additionally, conducting research across a wider range of geographies may produce more actionable recommendations for a variety of contexts.**

Similarly, understanding the barriers that providers face in offering oral PrEP and how these affect patient uptake and use are key to improving services, but few of the projects/studies contribute to answering these questions. Furthermore, the small scale of many projects may limit the applicability of findings to large-scale national rollout. Collectively, all of these factors suggest that current oral PrEP studies should prioritize research in the areas of provider support and values clarification, end user preferences for service delivery and generating demand for HIV prevention, and supply chain management; these could greatly inform many of the key challenges that oral PrEP projects/studies are faced with today as well as anticipated challenges of next generation PrEP.